

Future Directions in Disclosure Practices

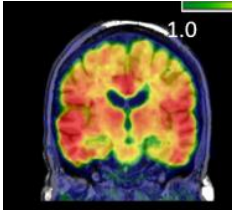
Lindsay Clark, PhD

Assistant Professor / Clinical neuropsychologist

Wisconsin ADRC Clinical Core Co-Leader

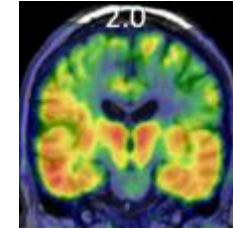
Wisconsin ADRC

ADRC PET disclosure practices



Amyloid PET

- **19 sites (53%) currently disclose results**
 - 11 routinely
 - 8 sometimes
- **17 sites (47%) do not disclose results**
 - Not part of original study design
 - Potential harms to participants
 - Time/burden on staff or personnel shortage
 - Results not clinically actionable or do not meet clinical regulations



Tau PET

- **6 sites (17%) currently disclose results**
 - 4 sometimes
 - 2 rarely
- **Additional reasons for not disclosing results**
 - Fewer sites collecting these data
 - Concerns about validity of cutoffs and meaning of results

Protocol Development

Process for learning results

Risks/benefits for learning results

Research Participant Information and Consent Form Addendum
University of Wisconsin-Madison
Study Title: Amyloid and Tau Imaging in Alzheimer's Disease

Participant Consent Addendum

Participant name _____ ADRCA or WIRAPM (circle one)

You are currently enrolled in the research study, "Amyloid and Tau Imaging in Alzheimer's Disease". The purpose of this research study is to collect images of amyloid plaques and neurofibrillary tangles that may be present in your brain. Amyloid and tau pathology are hallmarks of Alzheimer's disease (AD). Researchers evaluate how these Alzheimer's-related problems in the brain change over time and how they relate to memory and thinking, genetics, health, and lifestyle. The ability to image these processes in individuals may allow researchers to better understand why some people develop AD.

The information in this consent form addendum will help you decide whether or not you would like to participate in a substudy that would allow you to receive the results of your amyloid PET scan. This form should only be completed after reviewing and signing the main study consent form.



PHQ-4
Suicidality screen

In person
Televideo (HIPAA-compliant platform)

What You Need to Know about Amyloid PET Results

A guide for research participants



Your amyloid level was measured by a PET Scan on _____ (DATE)

Your brain amyloid test result was:

Elevated Not Elevated

Amyloid Test Summary Points

- What does it mean if my amyloid scan result is **Elevated**?
 - The scan detected amyloid plaques in your brain.
 - This result means that your mild cognitive impairment may be at least partially caused by Alzheimer's disease.
 - Your result means you are at an increased risk of developing dementia due to Alzheimer's disease. It is not possible to provide specific information on your exact amount of risk based on this result.
 - This result cannot determine if you have other changes occurring in your brain such as vascular disease, Parkinson's disease, or Lewy body disease.
- What does it mean if my amyloid scan result is **Not Elevated**?
 - The scan did not detect amyloid plaques in your brain. This result means Alzheimer's related brain changes were not detected at this time.
 - It is possible that amyloid plaques are present but not at an elevated level.
 - You are not at an increased risk at this time for developing dementia due to Alzheimer's disease based on your scan result.
 - This result only shows amyloid levels at the time the test was done. It is possible that your amyloid levels or risk could change in the future.
 - This result does not change your diagnosis of mild cognitive impairment but may mean there are other factors contributing to your cognitive impairment.

PHQ-4
Suicidality screen

Impact of test result
questionnaire

Dementia risk-reduction visit

Community supports visit

Satisfaction survey

Informed consent addendum

PET Scan

Mental health screening / scheduling

Education / Disclosure visit (approx. 3-6 months after scan)

Post-disclosure wellness check (1-3 weeks)

Post-disclosure additional visit (optional)

Post-disclosure satisfaction survey (optional)

Protocol Adaptions

Process for learning results

Risks/benefits for learning results

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Informed consent addendum

Best practices for providing brief, yet effective pre-testing and disclosure education?

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Elevated Not Elevated

Amyloid Test Summary Points

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 - This result only shows amyloid levels at the time the test was done. It is possible that your amyloid levels or risk could change in the future.
 - This result does not change your diagnosis of mild cognitive impairment but may mean there are other factors contributing to your cognitive impairment.

Education / Disclosure visit

Protocol Adaptions

Best practices for communication of result?

- Verbal + written report
- Contextualizing with clinical stage / known risk factors
- Visual image?
- Ensuring understanding / teach-back as needed
- Q&A



What You Need to Know about Amyloid PET Results

A guide for research participants



▶ Your amyloid level was measured by a PET Scan on _____ (DATE)

▶ Your brain amyloid test result was:

Elevated Not Elevated

Amyloid Test Summary Points

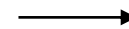
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Education (Coordinator)
/ Disclosure (Clinician)

Protocol Adaptions

How much post-disclosure support is needed? How can we create pathways and resources for participants?

- Clinical follow-up – emphasizing limitations of research results and considerations for sharing with medical providers
- Mental Health Services
- Health Behavior/Lifestyle Recommendations
- Advanced Planning Services
- Caregiver Support
- Educational Resources



PHQ-4
Suicidality screen

Impact of test result
questionnaire

Dementia risk-
reduction visit

Community supports
visit

Satisfaction survey

Post-disclosure
wellness check
(1-3 weeks)

Post-disclosure
additional visit
(optional)

Post-disclosure
satisfaction survey
(optional)

Memory Concerns Assessment

It is important to have an assessment if you or others have noticed any changes with your memory, thinking, or other brain skills. Considerations on making your health and well being a priority by having an assessment.

What to bring to your appointment

1. Eye glasses and readers
2. Hearing aids
3. Dentures
4. Assistive devices: walker, cane, special shoes, TED stockings...
5. Prescription medication bottles, vitamins, and regularly used over the counter medications. Also bring pill boxes and medication dispensers you use.
6. Recent appointment summary documents, health history information, recent hospital discharge instructions, and brain scan results.
7. Advance directives, such as Power of Attorney for Healthcare, Living Will, Five Wishes Advance Directive, guardianship papers, and activation documents if you have them.
8. Insurance cards and driver's license (or valid photo ID)
9. Written questions and concerns.
10. A family member or friend who knows you well.

What to expect during your appointment

A visit to a WISN-affiliated memory clinic will include a physical exam, a review of your medical history, and tests that measure your memory, thinking, and problem-solving skills. Staff will ask you questions about your medications, sleep habits, mood, and ability to perform daily tasks. A doctor may ask you to undergo brain imaging scans and blood tests.

If it is helpful to a friend or family member who knows you well accompany you to your appointment after your assessment, clinic staff will explain the results either immediately after your appointment or during a follow-up visit. Based on your results, clinic staff will review options for treatment, including medications and healthy lifestyle recommendations. The clinic staff will also provide you with information about community support services for patients and families and other recommendations for maintaining independence and brain health.

LIVE A FULL LIFE
Lifestyle Recommendations to Maximize Brain Health

What's the best recipe to optimize brain health? Use a full diet, healthy exercise, sleep, stress reduction, and other all-natural brain boosters. The healthier someone is generally, the more likely that person is to stay cognitively healthy. While there is no guarantee a healthy lifestyle will decrease the risk of developing dementia, healthy living will certainly improve the odds of staying cognitively healthy. Here are some specific suggestions:

Physical and Leisure Activity

- Do activities of physical activity 3-5 times a week that raises your heart rate and increases your breathing rate to light to moderate.
- Pursue physical and leisure activities that are enjoyable and include gardening, walking, swimming, yoga, dancing, golf, fishing, etc. • The number of days you are active and more than that often has a significant correlation to beneficial cognitive activity.
- Focus on balance, strength, balance, and flexibility.

Cognitive Activity

- Engage in cognitive activities that you enjoy.
- Challenge yourself with crossword puzzles, Sudoku, and other games.
- Stay mentally active, read, watch, and other games.
- Keep up with technology.
- Engage in social activities you enjoy.
- Engage in educational opportunities.
- Talk with family and friends.
- Learn to relax and work through and learn to de-stress.

Eat Well

- Think about your health is good for your brain.
- The Mediterranean CASHA-BRAND Diet was shown to be one that has been associated with brain health.

Rest, Relaxation, and Sleep

- Maintain consistent bed and wake times.
- Limit napping to 30 minutes a day.
- Encourage daytime light exposure.
- Avoid sleep apnea or sleep apnea symptoms and breathe slow to baseline.
- Avoid alcohol, caffeine, and tobacco.
- Do cognitive exercises for the brain.
- Keep bedrooms cool and comfortable temperature.
- Practice relaxation, deep breathing, or other relaxation techniques.

Overall Health

- Think about your health is good for your brain.
- Monitor or healthy weight.
- Limit alcohol consumption (2 drinks/day for men, 1 drink/day for women).
- Monitor normal blood pressure.
- Monitor high cholesterol.
- If you smoke, talk to your healthcare provider and discuss options to quit.

WISN Alzheimer's Institute
Division of Behavioral Health and Community

Clinician / Staff Training

Recommendations from our study clinicians:

- Training on AD, biomarker testing and interpretation
- Hands-on learning and collaboration
- Patient-facing materials to facilitate communication
- Appropriate amount of time for visit

Erickson, et al., 2024. *J Prev Alzheimers Dis.*



Coordinator training and effort:

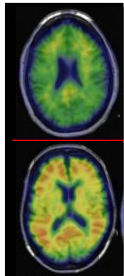
- Informed consent
- Mental health screening
- Pre-disclosure education
- Disclosure visit scheduling
- Post-disclosure wellness check or additional screening /questionnaires

Biomarker result interpretation

Current practice

Binary amyloid PET Result

- Elevated (Positive)
- Not Elevated (Negative)
- Based on visual read or SUVR cutoff



Future developments

More detailed quantitative information

- Centiloid value?
- High/Intermediate/Low?
- Estimated duration (e.g., chronicity)?



Challenge: *What exactly do these mean for prognosis or treatment? Need more information about how these values translate to specific prognostic or treatment recommendations.*

More biomarker tests

- Validation of clinically meaningful cutoffs for tau tracers and blood-based biomarker tests
- Communication of multiple biomarker results
- Lack biomarker tests for non-AD diseases (e.g., Lewy Body, TDP-43)
- Need more specific risk estimates



External validity – Cultural Considerations

Relationship between social determinants of health, health factors, and biomarker test results

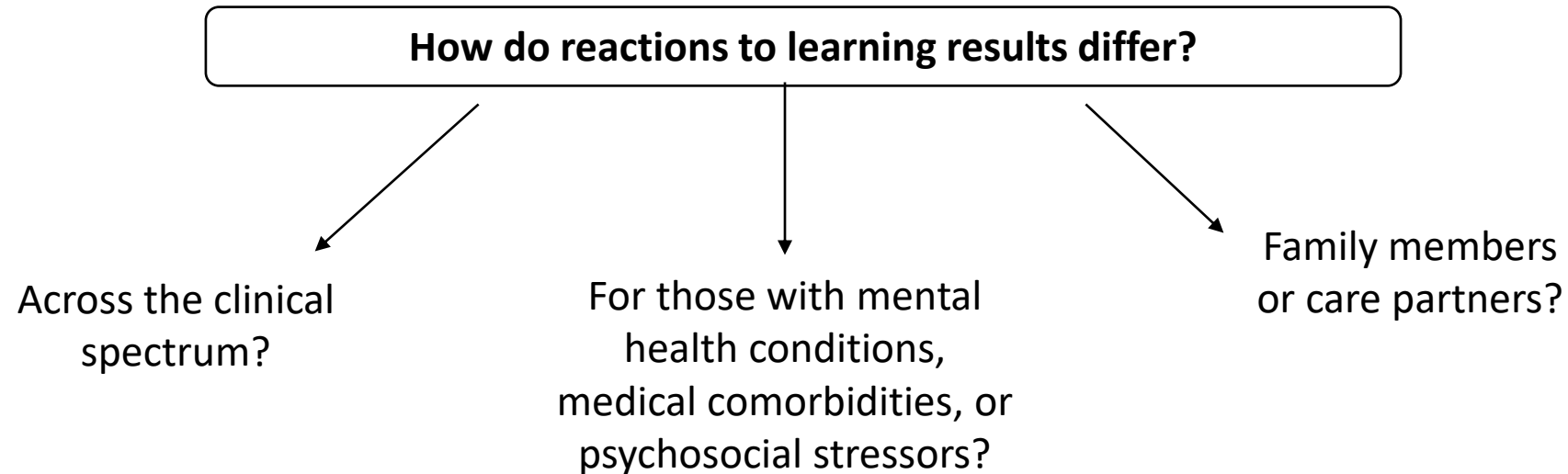
- Higher rates of clinical AD but lower rates of amyloid positivity in non-White participants (Wilkins et al., 2022 JAMA Neurology)
- Ethnoracial differences in plasma biomarkers associated with greater medical comorbidities (Meeker et al., 2023 A&D)

Cultural factors related to communication of results and recommendations

- There is a need for both protocolized disclosure AND site-specific cultural adaptation
- Solicit iterative feedback from community partners and advisors, as well as past participants, loved ones, and clinicians



External validity – Heterogeneous samples



Does learning results impact:

- Stigma
- Coping self-efficacy
- Cognitive symptoms/performance
- Future time perspective
- Perceived risk for dementia
- Understanding of diagnosis or prognosis
- Seeking evaluation or treatment
- Health behavior change
- Advanced planning

Available Resources

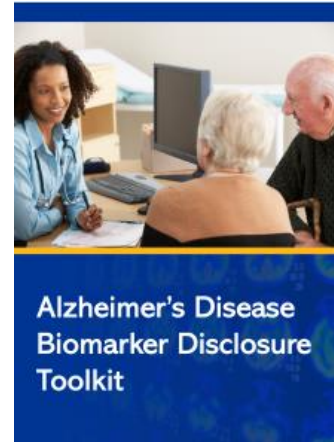
THE NIA ALZHEIMER'S DISEASE RESEARCH CENTERS PROGRAM

National Alzheimer's Coordinating Center

<https://nacccdata.org/adrc-resources/best-practices>



Biomarker Disclosure Guidance Document



Pittsburgh ADRC Toolkit
<https://www.adrc.pitt.edu/for-researchers/biomarker-disclosure-toolkit/>

Testing for Alzheimer Disease Biomarkers and Disclosing Results Across the Disease Continuum

Emily A. Largent, JD, PhD, RN, Joshua D. Grill, PhD, Kyra O'Brien, MD, David Wolk, MD, Kristin Harkins, MPH, and Jason Karlawish, MD

Correspondence
Dr. Largent

Largent et al., *Neurology* 2023 article



Webinars
Decision tools
Working groups

CLARiTI biomarker disclosure toolkit



53% of sites already disclose amyloid PET results (some routinely, some occasionally)

- If sites already have disclosure processes in place, can continue to use those processes for CLARiTI participants

For sites who do not currently return biomarker results, or want to supplement current processes:

Consent form language

Research Participant Information and Consent Form Addendum
for Results Disclosure

CLARiTI

TITLE: The ADRC Consortium for Clarity in ADRC Research Through Imaging

PROTOCOL NO.: 2023-1533
WCG IRB Protocol #20235657

SPONSOR: University of Wisconsin Madison

You are currently enrolled in the research study "The ADRC Consortium for Clarity in ADRC Research Through Imaging (CLARiTI)" and received an amyloid and/or tau PET scan. Amyloid and tau are hallmark proteins of Alzheimer's disease (AD) and may be visible on the brain PET scans you received.

The information in this consent form addendum will help you decide whether or not you would like to receive the results of your amyloid and tau PET scans. This form should only be completed after reviewing and signing the main study consent form.

If I decide I would like to receive my results, what is the process?
PET scan results may have meaningful information about whether you do or do not have Alzheimer's disease changes in your brain. These results may be disclosed to you if you choose to learn the results, and, if you meet screening criteria.

Educational materials

What You Need to Know about Amyloid PET Results
A guide for research participants




For people with mild cognitive impairment or dementia

What does an "elevated" or "positive" test result mean?

- An elevated test result means the scan detected amyloid plaques in your brain.
- An elevated test result cannot definitively confirm or diagnose the cause of your cognitive impairment; however, it does suggest the likelihood that Alzheimer's disease is a cause.
- If you have mild cognitive impairment, you have an increased risk for developing dementia due to Alzheimer's disease. It does not mean you will definitely develop dementia from Alzheimer's disease.

What does a "non-elevated" or "negative" test result mean?

- A non-elevated test result means the scan did not detect amyloid plaques in your brain. This result means brain changes indicative of Alzheimer's disease were not detected.
- It is possible that amyloid plaques are present but not at an elevated level.
- An individual may still develop elevated amyloid or dementia due to Alzheimer's disease in the future.
- A non-elevated result does not change the fact that you have mild cognitive impairment or dementia; it does mean that the cause is likely something other than Alzheimer's disease.

For people who are cognitively unimpaired

What does an "elevated" test result mean?

- An elevated test result means the scan detected amyloid plaques in your brain and therefore you have one of the protein abnormalities that defines Alzheimer's disease.
- An elevated test result means that you are at higher risk of developing cognitive changes and eventual dementia in the future. However, it does not mean that you definitely will.

What does a "non-elevated" test result mean?

- A non-elevated test result means the scan did not detect amyloid plaques in the brain. This result means brain changes indicative of Alzheimer's disease were not detected.
- It is possible that amyloid plaques are present but not at an elevated level.
- You may still develop amyloid plaques in the future.



Participant result summary report

> Your amyloid level was measured by a PET Scan on _____ (DATE).

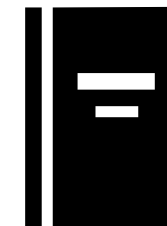
> Your brain amyloid test result was:

Elevated Not Elevated

Amyloid Test Summary Points

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 - It is possible that amyloid plaques are present but not at an elevated level.
 - You are not at an **increased risk** at this time for developing dementia due to Alzheimer's disease based on your scan result.
 - This result only shows amyloid levels at the time the test was done. It is possible that your amyloid levels or risk could change in the future.
 - This result does not change your diagnosis of mild cognitive impairment but may mean there are other factors contributing to your cognitive impairment.

Staff training manual



Forms/Scripts

- ✓ Assessing readiness
- ✓ Conducting disclosure visits
- ✓ Resources for next steps

CLARiTI disclosure toolkit development

Develop and test with pilot sites

Collaborate with Inclusion Core for participant input

Finalize toolkit and disseminate through NACC

Add tau PET disclosure materials once available

Update toolkit materials based on preliminary feedback



*Individual consultation with Disclosure Consultation Team

Acknowledgements

Wisconsin ADRC and WRAP participants who volunteer their time to help us learn more about AD!



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WRAP: NIA R01 AG027161 (Sterling Johnson)

WADRC: NIA P30AG062715 (Sanjay Asthana)

Contact information: lrclark@medicine.wisc.edu

Website: www.clarklab.medicine.wisc.edu

